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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/519,922 | 01/03/2005 | Christopher William Murray | BJS-620-354 | 7727 |

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| EXAMINER | |
|---|---|
| TUCKER, ZACHARY C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1624 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,922 | MURRAY ET AL. | |
| | Examiner | Art Unit | |
| | Zachary C. Tucker | 1624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C § 133) Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 4Mar05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Lack of Unity of Invention***
***~and~***
***Election of Species***

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 35 U.S.C. 372:

I. Claims 1 and 3-28 (all in part), drawn to compounds of formula I wherein the "X=Y" portion of the ring is $-CR^2=CR^3-$, classified in class 546, subclass 290, and pharmaceutical composition comprised thereof. These compounds comprise a pyridine ring as the core heterocyclic moiety.

II. Claims 1 (in part), 2 (not in part) and 3-28, drawn to compounds of formula I wherein the "X=Y" portion of the ring is $-CR^2=N-$, classified in class 544, subclass 408, and pharmaceutical composition comprised thereof. These compounds comprise a pyrazine ring as the core heterocyclic moiety.

III. Claims 29-32 (all in part), drawn to "use" of a compound as set forth in Group I hereinabove, and also drawn to a method for treatment of a condition ameliorated by the inhibition of p38 MAP kinase by administering a compound as set forth in Group I, classified in class 514, subclass 345.

IV. Claim 29-32 (all in part), drawn to "use" of a compound as set forth in Group II hereinabove, and also drawn to a method for treatment of a condition ameliorated by the inhibition of p38 MAP kinase by administering a compound as set forth in Group II, classified in class 514, subclasses 252.1 and 255.05.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the instant case, the Requirement for Restriction between Groups I and II (the compounds and compositions) is proper because the compounds are not chemically obvious variants of one another and comprise completely different core heterocycles.

The Requirement for Restriction between the compounds and compositions and the methods of "use" and method of treatment which corresponds with the Group of compounds employed in said "use" and method is based upon the fact that the examination of one such Group and its corresponding method and "use" will raise different non-prior art issues under 35 U.S.C. 101 and 35 U.S.C. 112, as stated hereinabove in point "e," because examination of medical treatment methods and "uses" involve considerations under those two statutes which are not typically encountered in examination of claims drawn to chemical compounds *per se*.

*This Requirement is Further Set Forth as Follows*:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be

applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. Subsequent to applicants'

election of species, the search and examination will proceed as set out in MPEP 803.02 under the heading "Markush Practice."

*This Requirement is Subject to the Following Conditions*:

The examiner has required restriction between compounds and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method of use claims that depend from or otherwise include all the limitations of the patentable compound** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and method of use claims will be withdrawn, and the rejoined method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims, method of use claims may be maintained. Withdrawn and method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Comments***

As courtesy to applicants, in the interest of compact and speedy prosecution of the instant application, the examiner would like to inform them of the prospective rejection of claims 29-32 in Group III or Group IV, which will likely occur upon rejoinder of those claims, at such time that those claims become eligible for rejoinder upon allowance of the elected Group I or Group II (only if either Group I or Group II is indeed elected by applicants).

As can clearly be seen from a review of the attached reference, cited hereinbelow, authored by Goldstein and Gabriel, only certain utilities were understood by those of

ordinary skill in the medical arts at the time of invention (physicians, in other words) to be connected with the inhibition of p38 MAP kinase.

> Goldstein and Gabriel "Pathway to the Clinic: Inhibition of P38 MAP Kinase. A Review of Ten Chemotypes Selected for Development" Current Topics in Medicinal Chemistry, vol. 5, pages 1017-1029 (2005).

Certainly, as applicants can appreciate, inhibition of p38 MAP kinase *in general* was not fully understood as a therapeutic/clinical intervention in the manner required by the "how to use" portion of the first paragraph of 35 U.S.C. 112 at the time the invention was made. Limiting the claims of either Group III or Group IV, however, to only treatment of an arthritic condition by administering either a compound as provided for in Group I or Group II, respectively, would obviate any prospective rejection of those claims under 35 U.S.C. 112, first paragraph.

***Conclusion***

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 9:00am to 5:00pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

ZACHARY C. TUCKER
PRIMARY EXAMINER